Complete Summary

GUIDELINE TITLE

The diagnosis and management of soft tissue shoulder injuries and related disorders.

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). The diagnosis and management of soft tissue shoulder injuries and related disorders. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004. 66 p. [102 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

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** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Soft tissue shoulder injuries, including:

- Rotator cuff disorders, including impingement, subacromial bursitis, tendinosis, painful arc syndrome, partial or full thickness and massive tear of the rotator cuff, long head of biceps tendinosis or rupture, and calcific tendinitis
- Frozen shoulder (also known as adhesive capsulitis)
- Glenohumeral (GH) instabilities, including acute and recurrent dislocation and labral injury
- Acromioclavicular (AC) joint disorders, including dislocation and stress osteolysis
- Sternoclavicular (SC) joint disorders, including sprain and dislocation.

GUIDELINE CATEGORY

Diagnosis

Evaluation

Management

Rehabilitation

Treatment

CLINICAL SPECIALTY

Emergency Medicine

Family Practice

Internal Medicine

Orthopedic Surgery

Pediatrics

Physical Medicine and Rehabilitation

Sports Medicine

INTENDED USERS

Patients
Physical Therapists
Physicians

GUIDELINE OBJECTIVE(S)

To provide an evidence-based summary of the diagnosis and management options available for soft tissue shoulder injuries and related disorders to assist health practitioners and consumers to make informed decisions to improve health outcomes

TARGET POPULATION

Adolescents and adults in New Zealand with soft tissue shoulder injuries and related disorders

Note: The guideline specifically excludes fractures, inflammatory and degenerative arthritic conditions, endocrinological and neurological conditions, hemiplegic shoulder, and chronic pain, including occupational overuse disorders.

INTERVENTIONS AND PRACTICES CONSIDERED

<u>Diagnosis</u>

- 1. History
- 2. Physical examination
- 3. Neurological examination
- 4. Imaging
 - X-rays
 - Diagnostic ultrasound
 - Magnetic resonance imaging (MRI)

<u>Management</u>

- 1. Medications including paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections
- 2. Sling
- 3. Activity modification
- 4. Specialist referral as indicated
- 5. Surgery
- 6. Consideration of the particular needs of Maori and Pacific Island patients

Rehabilitation

- 1. Physiotherapy including electrotherapy and exercise therapy
- 2. Acupuncture

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of clinical and diagnostic tests
- Rate of treatment success
- Disability at 6 months
- Quality of life and return to work

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic search of the literature was undertaken to identify relevant studies. Inclusion and exclusion criteria were applied to select the studies to be used in the guideline. Comprehensive searching was undertaken in general databases such as Medline, CINAHL, EMBASE, AMED, SPORTDiscus, Current Contents and in Cochrane Library [Systematic Reviews, Controlled Trials Register, Database of Abstracts of Reviews of Effectiveness (DARE)]. For this guideline, only meta-analyses, systematic reviews and randomised controlled trials were considered for treatment interventions. Only published studies in the English language were considered for inclusion.

Reference lists of included studies and relevant reviews were checked for further trials. Key words used in the search strategy are listed in the evidence document (available at the New Zealand Guidelines Group Web site), which also contains evidence tables for the included studies.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Therapy

The Guideline Development Team ranked the evidence according to the revised system of the Scottish Intercollegiate Guidelines Network (SIGN). Evidence statements relating to interventions have been assigned a grading according to the "strength" of the supporting evidence, where 1 is the best quality evidence and 4 is expert opinion.

1 + +

High quality meta-analyses, systematic reviews of radomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+

Well conducted meta-analysis, systematic reviews of RCTs, or RCTs with a low risk of bias

1-

Well conducted meta-analysis, systematic reviews of RCTs, or RCTs with a high risk of bias

2++

High quality systematic review or case-control or cohort studies; high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+

Well conducted case-control of cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2-

Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Nonanalytic studies (e.g., case reports, case series)

4

Expert opinion (e.g., narrative reviews, expert panel)

Note: Level of evidence [4] in this guideline includes both published expert opinion and the consensus of the Guideline Development Team.

Levels of Evidence for Diagnostic Tests

Single Diagnostic Studies

D++ Good: All four diagnostic tests' criteria met

D+ Fair: One or two of the criteria not met

D- Poor: None of the criteria met

Diagnostic Systematic Reviews

DSR++ High quality meta-analysis or systematic review of diagnostic studies

DSR+ Fair quality meta-analysis or systematic review of diagnostic studies

DSR- Poor quality meta-analysis or systematic review of diagnostic studies

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Individual studies were critically appraised and assessed for methodological quality using the Generic Appraisal Tool for Epidemiology (GATE) and assigned a quality rating.

The evidence from identified literature was summarised into evidence tables. The New Zealand Guidelines Group (NZGG) evidence tables are available at NZGG Web site.)

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In February of 2003, New Zealand Guidelines Group (NZGG) convened a multidisciplinary team of stakeholder groups and consumers to develop the guideline chaired by Associate Professor Bruce Arroll, (Dept of General Practice and Primary Health Care, University of Auckland) with Gillian Robb (Effective Practice, Informatics and Quality Improvement [EPIQ] Group, University of Auckland) as full-time project manager. Team members were nominated by stakeholder groups and invited to take part. The team held two major meetings during the year and several shorter meetings to discuss aspects of guideline development.

At the first meeting the Guideline Development Team defined the clinical questions and scope of the guideline.

A draft guideline was widely circulated to consumer groups, primary health care organisations, professional colleges and organisations, expert reviewers, and other clinicians for peer review, and this was modified where possible, as a result of their feedback.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

The Guideline Development team agreed on the recommendations using a "Considered Judgment" form.

Α

The recommendation is supported by good evidence.

В

The recommendation is supported by fair evidence.

С

The recommendation is supported by expert opinion only (e.g., published consensus document).

ı

No recommendation can be made because the evidence is insufficient (i.e., evidence is lacking, of poor quality, or conflicting), and the balance of benefits and harms cannot be determined.

Note: The grades A to I are a measure of the strength of evidence underlying the recommendations and should not be construed as an indication of the relative importance of the recommendations.

In this guideline, Grade C refers to recommendations that were developed from published expert opinion (e.g., consensus documents). Expert opinion has only been cited where there was no higher level of evidence.

Good Practice Points (GPP)

Recommended practice based on the professional experience of the Guideline Development Team where there is no other evidence

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft guideline was widely circulated to consumer groups, primary health care organisations, professional colleges and organisations, expert reviewers, and other clinicians for peer review, and this was modified where possible, as a result of their feedback. (The expert reviewers who made comments on the draft were acknowledged by name in the guideline document.)

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the Levels of Evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) and Grades of Recommendation (A-C, I, and Good Practice Points) are given at the end of the "Major Recommendations" field.

Initial Diagnosis and Management

Recommendation*

A If a significant rotator cuff tear is suspected, refer for diagnostic ultrasound.

Good Practice Points**

Diagnostic ultrasound should be undertaken by a radiologist with appropriate expertise.

Indications for radiography

- Strong suspicion of fracture
- Dislocation if aged >40 years or if clinically indicated
- Where surgery is being considered as a management option

Recommended views

- Anteroposterior (AP) glenoid fossa (Grashey) view
- Outlet or lateral scapular view
- Axial view

Plain films are best requested by a specialist, for people referred with shoulder problems that have not responded to nonoperative management or where surgery is being considered as a management option.

Refer people with red flags immediately for specialist evaluation.

Refer people with displaced and/or unstable fractures, massive tears of the rotator cuff, severe dislocations, and failed attempts at reduction urgently for specialist evaluation.

Rotator Cuff Disorders

Recommendations*

B Prescribe nonsteroidal anti-inflammatory drugs (NSAIDs) with caution. They provide short-term symptomatic pain relief, but can have serious consequences.

B Use subacromial corticosteroid injection with caution. It provides short-term symptomatic relief for people with tendinosis and partial thickness tears.

B Provide a trial of supervised exercise by a recognised treatment provider for people with rotator cuff disorders.

B Avoid use of therapeutic ultrasound (no additional benefit over and above exercise alone).

Good Practice Points**

Simple analgesics provide pain relief with less potential for serious side effects.

Informed consent for subacromial steroid injection should include the risk of infection (very rare), transient red face particularly in women, and sometimes "post-injection flare of pain."

Subacromial corticosteroid may be appropriate for full thickness tears as part of long-term management where surgery is not being considered as a treatment option.

If there is no significant improvement in those with a full thickness tear of the rotator cuff after 4 to 6 weeks of nonoperative management, refer to an orthopaedic specialist.

Early surgical management for a rotator cuff tear has the most to offer people with otherwise healthy tissue and who are physiologically young and active.

Frozen Shoulder

Recommendations*

B Actively consider intra-articular corticosteroid injection performed by an experienced clinician in the painful phase of a frozen shoulder.

B If required, offer supervised exercise by a recognised treatment provider to improve range of movement after the acute pain has settled.

Good Practice Points**

Informed consent for an intra-articular steroid injection should include likelihood of pain, the risk of infection (very rare), transient red face particularly in women, and sometimes "post-injection flare of pain."

People with diabetes should have their blood sugar levels monitored following corticosteroid injection and there should be appropriate contingency plans in place if hyperglycaemia occurs.

Avoid vigorous stretching in the early painful phase of a frozen shoulder as it will exacerbate pain.

It is most important that people with a frozen shoulder understand the time it takes for this condition to resolve.

Glenohumeral Instabilities

Recommendation*

A Young adults engaged in demanding physical activities with a first traumatic shoulder dislocation should be referred for orthopaedic evaluation.

Good Practice Points**

Investigations

- Prereduction x-ray is recommended in people aged >40 years.
- Post-reduction x-ray is recommended for all people with an acute first time dislocation to confirm the reduction and assess for bony injury.
- X-ray is required for all people with a failed attempt at reduction.
- X-ray is recommended for those with recurrent dislocation where surgical stabilisation may be a management option.

Acute Management

- Only clinicians with appropriate expertise should reduce anterior or posterior dislocations.
- Relaxation is critical for successful reduction. Ensure adequate analgesia is given, if required, before attempting reduction.
- Attempt slow steady traction for at least 30 seconds.
- Avoid excessive force while attempting to reduce a dislocated shoulder.
- Urgent referral to an orthopaedic specialist is required when reduction is unsuccessful after two attempts.

Post-Reduction Management: Nonoperative

- In people with a primary dislocation for whom nonoperative management is appropriate, apply a sling, provide analgesia, and refer for a supervised exercise programme.
- Following dislocation, people should not return to sport for at least 6 weeks, or when they have achieved near normal muscle strength.

Recurrent Dislocation

People with recurrent dislocation (>2) should be referred to an orthopaedic specialist to evaluate the need for surgical stabilisation.

Acromioclavicular (AC) Joint Disorder

Good Practice Points**

Imaging

• If surgery is an option for an AC joint dislocation, perform x-rays to stage the degree of dislocation.

Management

- People with Grade I and II sprains can be provided with a sling and analgesics for 5 to 7 days until comfortable.
- Advise gradual return to activity as symptoms settle, and avoidance of heavy lifting and contact sports for 8 to 12 weeks.
- People with Grade III AC joint sprains can also be managed nonoperatively but if this is not successful after 3 months, consider referral to a specialist for further evaluation.

• More serious AC joint dislocations require referral for orthopaedic evaluation.

Sternoclavicular (SC) Joints Disorder

Good practice Points**

Although rare, clinicians should watch for pulmonary or vascular compromise due to a posterior dislocation of the SC joint usually resulting from severe compression trauma. Immediate referral to an appropriate specialist is indicated.

Most injuries of the SC joint are mild sprains and can be managed with a sling, analgesics, and return to activity as tolerated.

<u>Cultural Considerations</u>

Recommendation*

C Health care practitioners providing care for Maori and Pacific peoples should be sensitive to their particular needs.

*Grades indicate the strength of supporting evidence, rather than the importance of the recommendations.

**Recommended practice based on the professional experience of the Guideline Development Team where there is no evidence available.

Definitions:

Levels of Evidence

1 + +

High quality meta-analyses, systematic reviews of radomised controlled trials (RCTs), or RCTs with a very low risk of bias

1 +

Well conducted meta-analysis, systematic reviews of RCTs, or RCTs with a low risk of bias

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Well conducted meta-analysis, systematic reviews of RCTs, or RCTs with a high risk of bias

2 + +

High quality systematic review or case-control or cohort studies; high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+

Well conducted case-control of cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2-

Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

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Nonanalytic studies (e.g., case reports, case series)

4

Expert opinion (e.g., narrative reviews, expert panel)

Grades of Recommendations

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The recommendation is supported by good evidence.

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No recommendation can be made because the evidence is insufficient (i.e., evidence is lacking, of poor quality, or conflicting), and the balance of benefits and harms cannot be determined.

Good Practice Points (GPP)

Recommended practice based on the professional experience of the Guideline Development Team where there is no other evidence

CLINICAL ALGORITHM(S)

The original guideline document provides a clinical algorithm for the diagnosis and management of soft tissue shoulder injuries and related disorders.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

This guideline has included a distillation of the literature of varying levels of evidence and where there is no evidence the guideline developers have recorded the expert opinion of the Guideline Development Team as Good Practice Points.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved diagnosis and management of soft tissue shoulder injuries and related disorders

Specific Benefits

- Simple analgesics such as paracetamol may provide adequate analgesia and have less potential for serious consequences than nonsteroidal antiinflammatory drugs.
- Intra-articular corticosteroid injection has a therapeutic effect in the early management of frozen shoulder compared with placebo.
- A supervised exercise programme has been found to lead to a faster improvement in the range of movement.
- Laser therapy may be beneficial in the treatment of frozen shoulder. There is some evidence that exercise and acupuncture, compared with exercise alone, may lead to better outcomes.

POTENTIAL HARMS

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with possible adverse effects including gastrointestinal bleeding, alterations in renal and platelet function, hepatitis, and bronchospasm.
- Possible adverse effects of corticosteroid injections include facial flushing in people with adhesive capsulitis, post-injection flare, infections (rare), tendon ruptures, hyperglycaemia in patients with diabetes.
- There are risks associated with reducing a dislocated shoulder, particularly in the older osteoporotic person, including fracture, and nerve and vascular damage. Reduction should therefore only be carried out by a person with appropriate knowledge, skill and experience. Avoid excessive force.

QUALIFYING STATEMENTS

QUALLEYING STATEMENTS

While guidelines represent a statement of best practice based on the latest available evidence at the time of publishing, they are not intended to replace the health practitioner's judgment in each individual case.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Two initial strategies will be undertaken to disseminate and implement the guideline.

- 1. The completed guideline and supporting material will be posted on the <u>New Zealand Guideline (NZGG)</u> and <u>Accident Compensation Corporation (ACC)</u> Web sites.
- 2. A laminated summary version of the guideline will be circulated to all groups involved in the diagnosis and management of soft tissue shoulder injuries. It will contain:
 - Key messages
 - Diagnostic and management flowchart
 - A basic shoulder examination

The Guideline Development Team suggests that ACC, NZGG and other relevant parties develop a detailed implementation plan.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). The diagnosis and management of soft tissue shoulder injuries and related disorders. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004. 66 p. [102 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUI DELI NE DEVELOPER(S)

New Zealand Guidelines Group - Private Nonprofit Organization

SOURCE(S) OF FUNDING

New Zealand Guidelines Group

GUI DELI NE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

New Zealand Orthopaedic Association - Professional Association New Zealand Society of Physiotherapists - Professional Association NZ Association of Musculoskeletal Medicine - Medical Specialty Society Royal Australian and New Zealand College of Radiologists - Professional Association

Royal New Zealand College of General Practitioners - Medical Specialty Society Sports Medicine New Zealand - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>New Zealand Guidelines Group Web site</u>.

Print copies: Available from the New Zealand Guidelines Group Inc., Level 30, Grand Plimmer Towers, 2-6 Gilmer Terrace, PO Box 10-665, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgq.org.nz.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 New Zealand Guidelines Group (NZGG). Key messages. The diagnosis and management of soft tissue shoulder injuries and related disorders. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004 Jul. 2 p. Available in Portable Document Format (PDF) from the <u>New Zealand Guidelines Group</u> Web site.

Print copies: Available from the New Zealand Guidelines Group Inc., Level 30, Grand Plimmer Towers, 2-6 Gilmer Terrace, PO Box 10-665, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 22, 2004. The information was verified by the guideline developer on January 17, 2005. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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